THE INTEGRITY OF THE PEER REVIEW SYSTEM AS USED AT THE NATIONAL INSTITUTES OF HEALTH

I. Background

From a level of approximately $35 million provided for the National Institutes of Health (NIH) in fiscal year 1950, the Federal investment for biomedical research in that agency has grown to over $2.5 billion in fiscal year 1977. With only minor perturbations overall growth has been steady, reflecting confidence in biomedical research for improvements in the health of our citizens and reaffirming the primary role of the Federal government in the support of advancing knowledge. From the time that the Federal role was established, support for research training has also been an explicit recognition that the long term vigor of the enterprise is dependent on a constant infusion of well-trained investigators. The consequence has been the creation of the world's foremost biomedical research endeavor as a unique partnership between the public sector and the biomedical science community.

To carry out the responsibility for the large-scale investment of tax-derived funds, the NIH developed a system for the allocation of its research funds. A key factor in the concept adopted was that prominent scientists active at the cutting edge of science in the laboratory or clinical setting were in the best position to assess the scientific merit of proposals submitted for Federal funding and to recommend those potentially most contributory to the objective of improving health through increasing new knowledge.

As the size of the research program expanded, the scientific members of the legislatively mandated National Advisory Councils soon were unable to cope with the research components of the grant applications, given the diversity and number of proposals submitted. To meet the new demands the NIH created by administrative action a two tier review system that, with refinements, is still in use. This arrangement consists of: 1) discipline or specialty oriented initial review groups (IRG's), comprised of recognized experts in those areas and charged with assessing the scientific quality of each grant application, and 2) legislatively mandated National Advisory Councils, including both scientific and lay personnel, which had been assigned the task of recommending those proposals deemed most worthy of the investment of Federal funds. This system has been repeatedly examined by a variety of prestigious groups and has invariably been acclaimed as serving the public interest extraordinarily well in allocating Federal funds for research. In fact other research supporting organizations in both the public and private sectors have emulated the NIH concept

and system. Most recently the Congress has seen fit to explicitly mandate review by a peer system for various types of research programs.

It should be noted that the overall grant application review system at NIH also represents one of the best bargains currently available to the Federal government. Present estimates place the cost of that system at about one dollar for every $100 requested. Were the NIH forced to reimburse the individuals constituting these panels for the total time expended in the preparation for application review and at the rate they are able to command as consultants or to expand its own staff to encompass the review responsibility, the cost would be enormously greater.

Despite minor criticisms -- which for the most part have been successfully refuted -- the system has withstood the test of time. It is not surprising, therefore, that threats to it, arising either externally or internally, are viewed within the scientific community and elsewhere with the gravest concern.

II. The Problem

Several recent developments together with longstanding governing principles have converged to cause a strikingly serious overloading of the NIH grants review system that constitutes in the opinion of long-time, well-informed observers, the most ominous threat to its integrity that the system has faced since its inception. The elements, cited below, contributing to this situation are several:

- A significant increase in the capacity of the biomedical research enterprise in this country over the past ten years. This has been a planned and purposeful expansion on the part of the Federal government, involving not only increases in funds appropriated for research but the establishment and support of a large-scale research training enterprise also financed with Federal funds.
- An almost doubling in five years of the number of research grant applications reviewed by the NIH (Figure 1). The evidence available suggests a strong relationship between this phenomenon and the expansion of the research training programs which was initiated in the mid-60's. Therefore, the first and most important influence is the increase in the number of scientists who are now able to compete for existing funds. The second is the uneasiness within the scientific community concerning the inconstancy of Federal programs and funding during the past few years

and the increased competition within the system. Discussions with numerous institution officials and individual scientists support the belief that these uncertainties in funding have prompted more numerous applications to NIH for the same project or parts of it in order to increase the chances of success in competition for the available funds.

- Reductions in position ceilings within the Executive Branch which, in the case of the Division of Research Grants (DRG), NIH, have resulted in fewer employees to staff the Study Section operation than was true a decade ago (Figure 1).

- The zealous implementation of the Federal Advisory Committee Act and Presidential directives to reduce the number of advisory committees in the Executive Branch (Figure 2).

- Interpretations of the Privacy Act by the General Counsel, Department of Health, Education and Welfare (DHEW) which permit individual principal investigators to request access to their application review files at any time during the review process and to submit amendments and rebuttals to the evaluations the application has received.

- Continuing intra-departmental scrutiny of the legitimacy of the statutory grounds (in the Freedom of Information Act and the Federal Advisory Committee Act) for declining to release applications prior to funding and for conducting the Study Section (IRG) review of applications in closed session appear on the verge of destroying a level of confidentiality viewed as essential to the effective operation of the system.

- The tradition of the American scientific community and the Federal government that every qualified scientist has free and open access to compete for public funds for research.

III. The Consequences

While any of several of these influences would have created serious problems, the aggregation of all of them has resulted in a devastating impact on the system, a severe erosion of the capability for effective and timely scientific review, and a situation that will certainly worsen significantly unless immediate and major corrective steps are undertaken. Some of the specific consequences can be identified as follows:

- The workload on individual Study Section members in preparation for the three meetings per year has vastly increased. It should be noted that these individuals are practicing scientists whose career advancement depends on their personal productivity in research and that they are the same individuals who must spend more time in paperwork -- such as more detailed and time-consuming preparation of applications and progress reports -- associated with securing their own research support.

  Although the program managers of the peer review system for project grants at NIH conclude that, on the average, Study Section workloads should not exceed approximately 225 to 240 applications per year, recent years have seen that average rise steadily to the level in 1977 of 355 applications per Study Section. In rapidly developing scientific areas, the number is significantly greater.

- Resignations by Study Section members have increased sharply over the past three years, from four in 1974 to thirty one in 1976. There have also been larger numbers of formal declinations by qualified individuals to serve on initial review panels. Additionally, we are told that in some institutions and professional organizations, younger scientists are being discouraged from accepting appointments to Study Sections as being too demanding of their time. This circumstance is the obverse of that in previous years when such service was a coveted honor and important in the advancement of a biomedical scientist's career.

- The access provision of the recent Privacy Act, as interpreted by the DHEW Office of General Counsel, permitting unrestricted access to the application files by the principal investigator, is now used extensively by individual scientists as an informal appeals mechanism. During the 1977 fall review cycle, almost 1,300 grant summary statements ("pink sheets") were requested, frequently before they were sent to the members of the Advisory Councils. This represented about one third of the applications under review at that time; the comparable number in 1976 was but a small fraction of that total. The result is a serious disruption of the usually orderly process of grant application review, especially in the period between Study Section consideration and Council review. Members of both initial review groups and Advisory Councils are being badgered by principal investigators concerning comments by site visitors or by Study Section members about the review of their applications prior to final recommendation by the Advisory Council.

- Because of the work overload, the Executive Secretaries of the Study Sections are unable to spend sufficient time in the preparation of the all-important pink sheets and other pertinent staff activities related to the review system. The latter include, for example, the identification of applications involving DNA research or human subjects and review for assurance of conformance with current agency policies. Furthermore, the fact that they are subject to disciplinary action for improperly withholding information (under the Freedom of Information Act) and to criminal penalties for disclosing material (under the Privacy Act) to any person not entitled to receive it has created a working environment that is not conducive to effective and productive administration.

- This burden on the NIH staff, together with the similar overload on the consultants, especially at the initial review stage, must inevitably lower the quality of the review process.

IV. Possible Solutions

Generally speaking, solutions to the problem would involve a decrease in the number of applications submitted for review and/or an increase in the capacity of the system to handle the larger workloads. Numerous possibilities have been explored as potential solutions. Close examination, however, leads to the conclusion that no single action will suffice. Among ideas which are under consideration are the following:

- Relief from the ceilings on staff positions and numbers of Advisory Committees.

  -- The White House, the Office of Management and Budget, and the several levels of DHEW must be persuaded that the prevailing Executive and Legislative branch strictures on increases in both staff positions and the number of advisory committees are counterproductive in this instance and must be substantially modified. One way of doing it without appearing to backdown on highly trumpeted past achievements in reducing the number of Advisory Committees would be to invoke the concept of a flexible Study Section (in essence, a large panel of members constituting a given Study Section which could then be broken into several smaller groups); this seems to be gaining favorable attention within the Department. However, even if approved, there would still remain the very serious problem of staffing the sub-groups.

-- Wider use of the Intergovernmental Personnel Act and expert consultants under the authorities of the National Cancer Institute and the National Heart, Lung and Blood Institute to augment the number of Executive Secretaries staffing Study Sections. This approach is already being utilized in an effort to relieve the pressure on IRG staff. But individuals whose services are available under either of these approaches are necessarily limited in the duration of their assignments. A longer continuity of involvement is required for an individual to effectively fill an Executive Secretary role. Furthermore, there emerges a serious question as to the appearance or even actuality of a conflict of interest.

-- Reallocation within NIH of staff positions under existing ceilings. It is uncertain how feasible this approach might be. Total personnel ceilings at the NIH have fallen steadily over the last decade while program responsibilities have increased substantially. As the latter involve enlarged funding, complexity of programs and ancillary issues related to such problems as ethical considerations in the use of human subjects in research, Equal Employment Opportunity, refinement of accountability requirements, development of long-range planning documents, etc., there would not appear to be any significant existing source of positions which could be tapped without very deleterious consequences. To reduce the intramural research program staff for this objective would cripple and demoralize extremely important and productive scientific activities.

- Modifications in application processing by NIH

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-- Deferral of the final decision as to funding on those applications whose review has been interrupted by challenges before it has been completed (e.g. between Study Section and Council meetings). This approach apparently has been interdicted by DHEW legal staff on the basis that it would constitute a punitive measure against the principal investigators who challenge tentative recommendations.

unless requested.

-- Withholding documents requested under the Privacy Act (e.g. pink sheets) until review has been completed and a decision has been made to fund a particular proposal. It is uncertain whether this is feasible, in view of previous interpretations of the Act by at least some government counsels.

mail report Council. use telecons.

-- Limitation on the length of applications. A proposal to hold applications to an arbitrary length (e.g. 20 pages) might accelerate review and reduce the workload but could weaken the primary method of communication from the investigator to the reviewers.

-- Limitations on the number of applications submitted per principal investigator or per institution. The NIH should be justifiably reluctant to impose such limitations by directive, given the history of the Federal government's attitude toward the accessibility of appropriated funds to eligible grantee institutions and scientific investigators.

- Restraints within the grantee institution

-- Establishment by grantee institutions of formalized local screening systems to reduce the number of poorly executed or incomplete applications submitted to the NIH. Considerable doubt exists as to whether most institutions could constitute an effective screening process of this nature, especially without a directive from the NIH requiring such a prescreening phase.

-- Voluntary restraint by individual investigators in submitting applications and in requesting pink sheets prior to the completion of the application review. On the basis of discussions with individuals in the academic community, it seems highly unlikely that there would be sufficient response to a call for voluntary restraint on application submission by individual investigators and their institutional officials. The importance of grant support to investigators and the competition in the grant system at this time force the conclusion that unless voluntarism occurred simultaneously and to a significant degree in most grantee institutions there would be little effect. However, voluntarism might prove successful in reducing the number of premature requests for pink sheets.

V. Possible Actions

At the moment, the scientific community and other interested sectors of our society are largely unaware of the complexity and portentousness of this situation. It also seems certain that with that awareness there will be the same immediate and widespread concern which is held by the relatively few individuals who are cognizant of the overall situation at this time. It is important that there be developed a strategy to handle this multi-faceted problem so as to maintain the integrity of the

system as a matter of public good. Concommitantly, the strategy should avoid the possibility of inappropriate efforts by well meaning but poorly informed individuals or of arousing in critics the use of this set of circumstances to substitute a less effective approach to the allocation of Federal funds than the mechanism now used by the NIH. It is necessary, therefore, to examine efforts which the academic and scientific communities as well as the government might undertake. The following are recommended for consideration:

- Reaffirm support for the peer review system
  Leaders of the academic and scientific communities should publicly recommit themselves to the value to the public and to science of the peer review process and the need and value for qualified individuals, particularly among young investigators, to serve on initial review panels. The consequences of alternatives, such as total block grants or distribution on a geographic basis, should be explained.

- Inform the communities
  Basic to any successful effort is the need to broadly inform the scientific and academic communities as well as the public as to the nature and seriousness of this threat to the system. Undoubtedly, several different approaches will have to be made, including presentations and discussions at scientific meetings as well as articles in appropriate scientific and possibly other publications.

- Enhance the analysis of the research grants program
  While considerable effort has been expended by the NIH in maintaining statistics about the grants program, the current set of problems reveals the inadequacy of those efforts. It is suggested that NIH should expand its analytical activities so as to provide the basis for a better understanding of the dynamics of the program.

- Address the personnel requirements for the system
  This aspect involves staffing of the Study Section apparatus with more full-time positions as well as increasing the number of Study Sections and members. These changes will have to be approached in both the Legislative and Executive Branches. The Congress can speak to the need for expanding the capability of Study Sections to handle the workload but it is the Executive Branch through White House policy and action at several HEW levels that must implement the required changes.

o Eliminate the impact of the current interpretation of the Privacy Act

The requests for pink sheets and other documents by principal investigators prior to the completion of the review process should be interdicted by some method. Two possibilities exist:

-- Convince the Office of the General Counsel, DHEW, that either requests for pink sheets can be refused prior to final decision on the application or permit the application to be deferred until the next review cycle if a premature request for information is made, on the basis that the process has been disrupted and the application is incomplete, or

-- Seek legislative modification of the access provision of the Privacy Act.

o Establish a balance between competing public policies

Just as the approach to less secrecy in government is a desirable public objective, so is the assurance that the nation's scientific enterprises will flourish by being provided with an environment attractive to the best scientists and therefore conducive to the most productive research. At the present time, there appears to be an imbalancing of these oft times competing values in that under prevailing procedures, responses to demands for disclosure of research proposals submitted to the NIH and other Public Health Service agencies do not permit adequate protection for the ideas of individual scientists. Those ideas are the scientist's intellectual capital and his professional advancement is primarily dependent on them.

It is recommended that both the Congress and the Executive Branch review the present laws and regulations and their administration to determine in explicit terms the manner in which each of these policies should relate to one another. The solution to reconciling the conflict between these values to best serve the overall public interest would be a legislative shield under which research proposals would be protected from premature disclosure permitted by 5 U.S. Code, Section 552(b)(3).

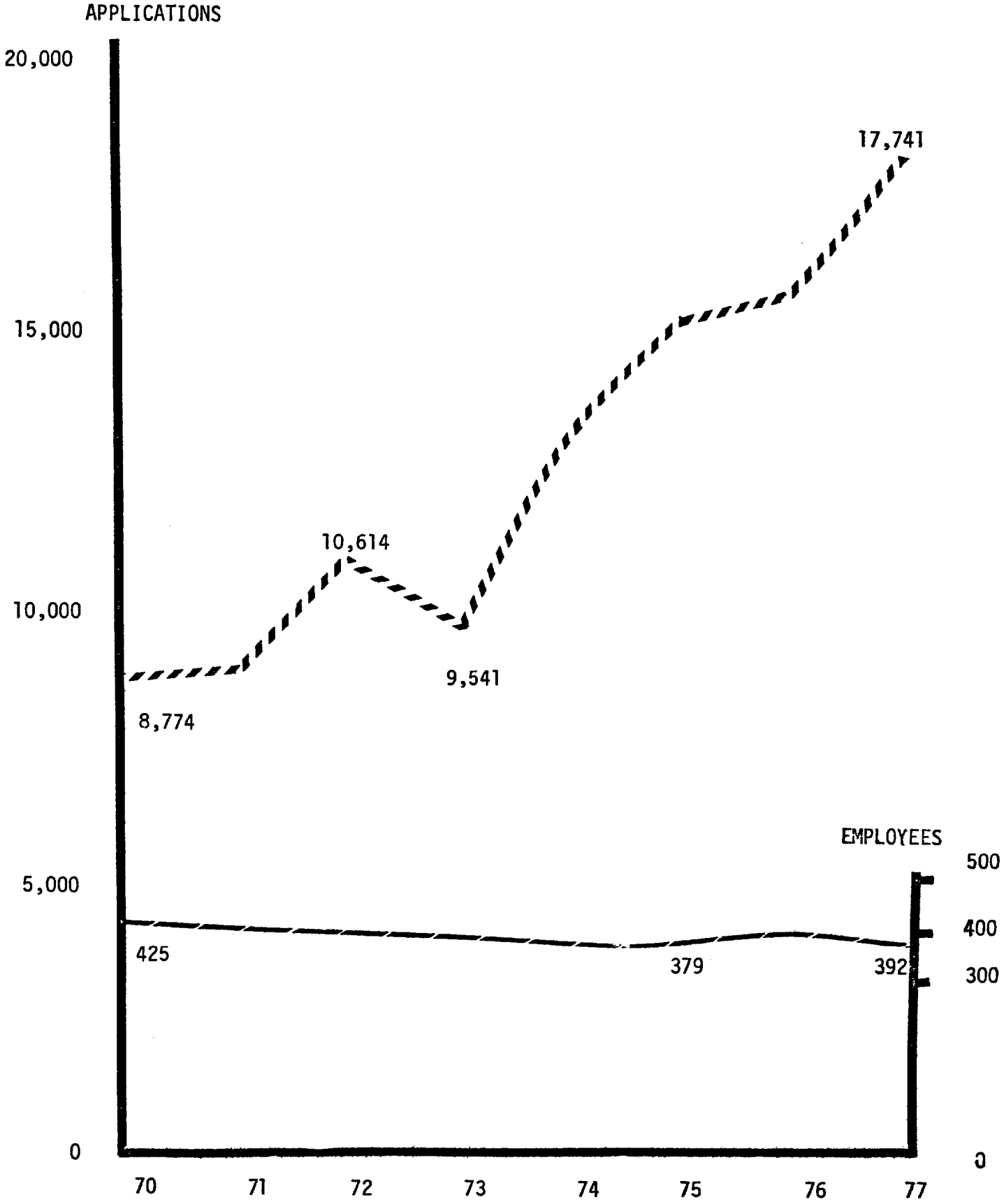
VI. SUMMARY

The effectiveness of the system of peer review used to allocate research funds appropriated for programs at the National Institutes of Health is severely threatened by a series of policies, events and circumstances which require immediate attention by the Executive Branch, the Congress and the scientific community. Failure to take prompt corrective measures for these problems could result in the destruction of a system widely acclaimed as both efficient and equitable, without the availability of an appropriate alternative mechanism.

Association of American Medical Colleges
May 15, 1978

APPLICATIONS REVIEWED AND NUMBER OF EMPLOYEES

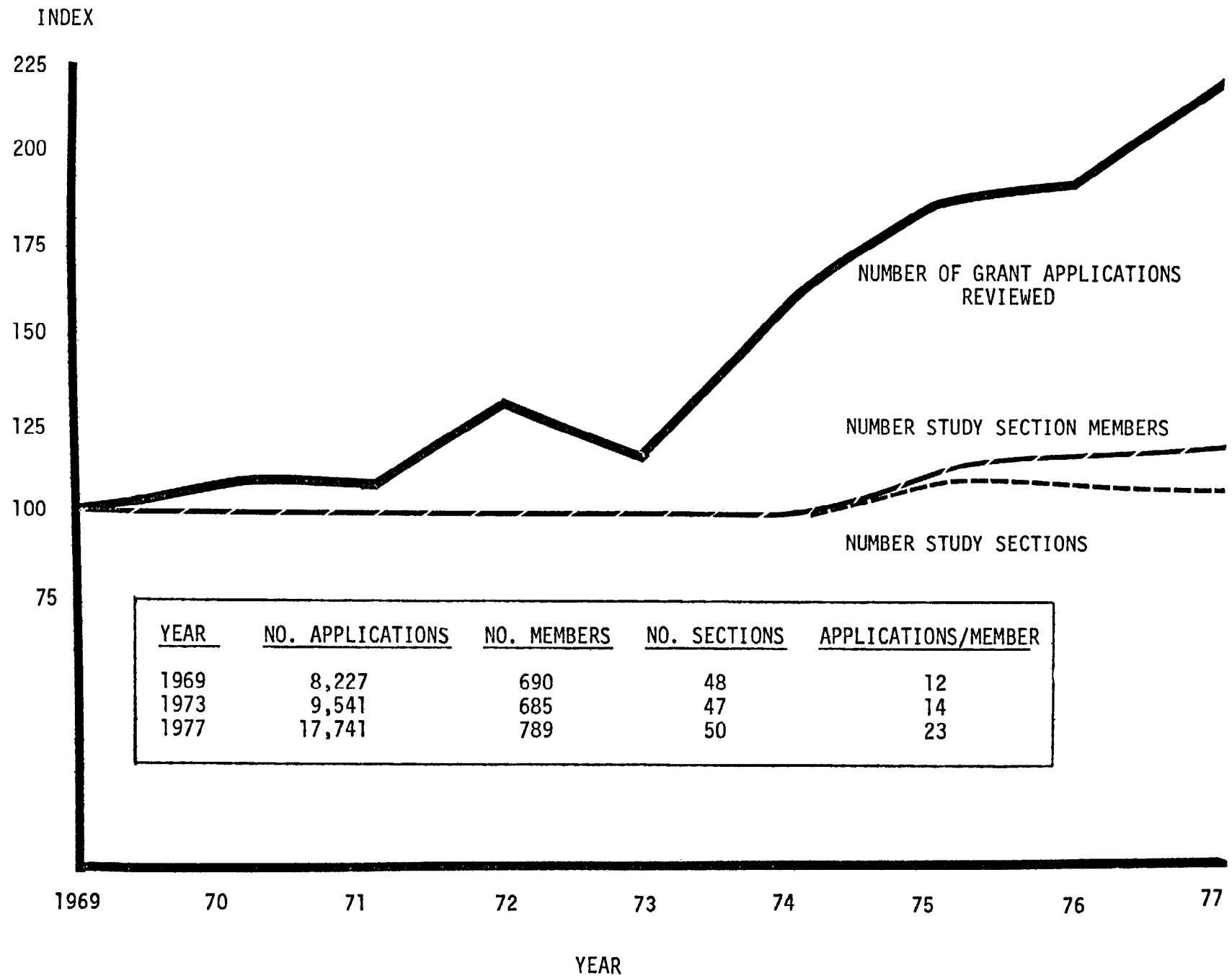
1970 - 1977



(Figure 1)

APPLICATIONS, STUDY SECTION MEMBERS AND STUDY SECTIONS

1969-1977



YEAR	NO. APPLICATIONS	NO. MEMBERS	NO. SECTIONS	APPLICATIONS/MEMBER
1969	8,227	690	48	12
1973	9,541	685	47	14
1977	17,741	789	50	23

(Figure 2)

Specific remarks keyed to text: JUL 14 1978

1. Has there been steady growth in real dollars?

2. Combination of truncated terms of awards and increasing red tape and delay/ lead time: many applicants are in a state of perpetual application anxiety. Particular impact on complex, interdisciplinary projects: have become almost impossible. Result is splintering of research into nothing but projects, tempered by traditional modes of scientific communication among experts in a discipline, but erosion of glue that holds an institution together.

3. I take serious and principled exception to the point made here and throughout. Investigators should have, if anything more, not less opportunity for feedback. Without that corrective, any system will become corrupt.

4. Obviously others are ready to fill the vacuum, who may have limited opportunity to exhibit their talents in constructive research. Worst of all, rebuffed and ressentient youngsters.

5. Individual badgering is of course a serious nuisance. The reviewers could be armed with a form letter from the Director NIH that such communications are an interference with the review process and that information not sent through channels must legally be disregarded, to the point where the reviewer should disqualify himself if he feels that his autonomy has been impaired by such communications.

6. If the councils met more often, and had better technical support, or if other means to sustain interim support were feasible, P.I.s could well REQUEST deferral for more info. In present circumstances, this is a disaster.

7. Sections could at least be admonished not to discredit short applications if there are effective references to previous literature and they come from established investigators. I have repeatedly been met with insistence that I include detailed accounts of experimental procedures that were in the literature!! Conversely, in another case, the meat of an application was a preprint of a paper in press, which staff refused to incorporate in the application because it had not been retyped as part of a conventional proposal.

8. Page 8. Yes I have to agree about these cautions and needs.

9. As before, vehemently NO. I agree about need for confidentiality of individual reviewers' names. But pink sheets are rife with unsupported assumptions about what an applicant meant by a given phrase, with factual errors (particularly about budgeting and institutional situations), and about the existing state of the literature. I do not have good solutions to these problems, but will at least advert to an appellate role of a COUNCIL-(based) mechanism, which must be made managerially brisker.

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